

REMARKS

Reconsideration is respectfully requested in light of the amendments above and the remarks that follow.

Claims 1-3 and 6-7 are before the Examiner. Claims 1-3 have been amended to more clearly set forth the invention and to better track with the arguments previously presented and also with those presented below. Certain claim limitations were deleted to address an obvious redundancy issue- "densified". The tamped density range conveys this. In light of the Examiner's comments, "solid and semi-solid" limitation were causing confusion. "[F]lowable" was added as a descriptor since it is a characteristic clearly demonstrated in the specification for the composition. Claims 6 (tablet) and 7 (capsule) have been added. The use of the composition of claim 1 in tablet and capsule preparation results in attendant improvements for both the tablet (hardness) and capsule (ease of preparation, more consistent activity between batches and capsule weight).

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimizu et al (USPPA 2002/0102369) as evidenced by Scholz et al. (USP 6951642). Applicants respectfully traverse.

The rejection was apparently maintained due to the presence of confusing claim terminology. That terminology has been deleted from the claim and replaced with "flowable", which is a more suitable descriptor.

This claimed subject matter is clearly not a cellulose ester film useful as a protective film for a polarizing plate taught by Shimizu et al. Shimizu et al do not mention a flowable cosmetic or pharmaceutical composition. In light of the amendments to claim 1, the evidentiary value of Scholz et al. is rendered moot.

Withdrawal of the rejection is respectfully requested in light of the amendments to claim 1.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shimizu et al (USPPA 2002/0102369) as evidenced by Schotz et al. (USP 6,951,642). Applicants respectfully traverse.

Shimizu et al. is not directed to a flowable pharmaceutical or cosmetic formulation. The AEROSIL product present in Shimizu et al product is a "filler". It does not impart "flowability". There are no pharmaceutically or cosmetically active compounds present in effective amounts. The silica employed by Shimizu et al. is "filler" for a coating and not a carrier or "auxiliary aid" for pharmaceutical or cosmetic composition.

Scholz et al. was discussed in the prior response. In light of the amendments to claim 1, its teachings appear less relevant.

Neither Scholz et al. or Shimizu et al. desire a flowable powder suitable for tableting or placement in a capsule.

It is not seen how "optimization" of any parameter taught in Shimizu et al. would lead to a flowable composition having the claimed tamped density range. The functions of the taught compositions are quite different, e.g. protective film v. "improved" flowability and tablet hardness.

Since a prima facie case has not been established, withdrawal of the rejection is respectfully requested.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sebillotte-Arnaud et al. (USPPA 200/0039976). Applicants respectfully traverse.

Sebillotte-Arnaud et al. teach a cosmetic cleansing composition which includes a foaming surfactant, a hydrophobic silica and a oxyalkylated compound. The hydrophobic silicas taught by Sebillotte-Arnaud et al. include AEROSIL products. None, however, are identified as AEROSIL R972 V. Further, the Sebillotte-Arnaud et al. cosmetic cleansing composition is not a flowable pharmaceutical or cosmetic formulation. It is clearly not a tablet or capsule.

It is noted that while Sebillotte-Arnaud et al. teach (paragraph [0021]) a preferred density range 50-150 g/l for compacted silica. The claimed range overlaps that range as noted by the Examiner. However, the claimed range produces a flowable pharmaceutical composition and hard tablets. These products are not taught by Sebillotte-Arnaud et al. Also, when compaction is employed for the purposes of Applicants' invention, grinding of the compacted product is required. Destructuring is not taught by Sebillotte-Arnaud et al.

Also, it appears from paragraph [0104] that the addition of the hydrophobic silica and oxyethylated compound thicken the cleaning composition and lead to better rheological properties. These compounds are not active ingredients.

The Examiner acknowledges that the Sebillotte-Arnaud et al. reference does not teach AEROSIL R972 V but urges that its selection and use in Sebillotte-Arnaud et al. composition would have been a obvious. No reference is relied upon for such a teaching. It is not clear why a more dense silica would be desired for Sebillotte-Arnaud et al.'s purposes. Obvious-to-try, by itself, is not statutory obviousness.

The present claims are believed to be commensurate in scope with the unexpected results presented in the specification. The results demonstrated in the specification would not be expected from the applied references.

AEROSIL R972 V (Tamped density (g/l)- 90) is a distinct from AEROSIL R972 (Tamped density (g/l)- 50). The Tables in the specification show the use of the different AEROSIL R972 products result in different outcomes. These differences would not be expected from the art of record. Also CP 1 and CP 2 establishes the criticality of the "water-wettable contents make up a max. of 3.0 wt %" limitation and also the density. See Tables 7 and 8. This too is unexpected. The tables in the specification, e.g. Table 7, show differences between the use of AEROSIL R972 V and AEROSIL R972 in terms of Pore cone height, Table hardness, Disintegration time and Capsule weight values. The values for AEROSIL R972 V are decidedly better.

Accordingly, it is again submitted that the teachings relied upon do not establish a proper prima facie case of obviousness. Further, the results shown for AEROSIL R972 V are not expected and are considered to rebut a prima facie case. The results shown in the tables are believed to be commensurate in scope with the claims as now amended.

Withdrawal of the rejection is respectfully requested.

Request for Interview

Applicants respectfully request either a telephonic or an in-person interview should there be any remaining issues.

CONCLUSION

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Therefore, it is respectfully requested that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. 1.136(a), and any fees required therefore are hereby authorized to be charged to **Deposit Account No. 02-4300, Attorney Docket No.: 032301.608.**

Respectfully submitted,

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